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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Peter Kinast

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EXAMINER

CARPENTER, WILLIAM R

ART UNIT

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3767

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/542,823	Applicant(s) KINAST ET AL.	
	Examiner WILLIAM CARPENTER	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 56-106 is/are pending in the application.
- 4a) Of the above claim(s) 88-106 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 56-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/26/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, Claims 56-87 in the reply filed on 30 July 2008 is acknowledged. The traversal is on the ground(s) that the prior art does not teach the alleged special technical feature shared by Groups I and II. This is not found persuasive because Applicant has not afforded the claims the broadest reasonably interpretation, has placed improper weight on functional language, and relies in part on features not found in the claims.

Further support for the finding of lack of unity can be found below under the section detailing claim rejections under 35 U.S.C. § 102.

In accordance with MPEP §806.05(f) should a product claim be found allowable the withdrawn process claims that require each and every limitation of the allowed product claim will be considered for rejoinder. Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 88-106 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 30 July 2008.

Priority

3. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 10/542823, filed on 20 July 2005.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 56-63, 65, 76-82, and 84 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 3,071,135 ("Baldwin").

Regarding Claim 56, Baldwin discloses a needle (10) for penetrating a membrane (B), having a pointed end provided with a penetrating tip (Figure 2) and with an opening (16) for letting a liquid in and/or out in a main direction which is substantially parallel to the longitudinal extension of the needle. Baldwin discloses that the penetrating tip is provided with a substantially point-shaped edge (14) to initially prick a membrane when the membrane is penetrated and that the outer edges (19 and 18) present on the pointed end in the area between the point-shaped edge and a position beyond the opening are rounded (Column 3, Lines 51-59) so that after the initial penetration the pointed end will push the membrane material away rather than cutting the membrane (Column 3, Lines 59-65).

Regarding Claim 57, Baldwin discloses that the inner edge (18) of the opening is rounded.

Regarding Claims 58-61 and 76-79, Baldwin discloses that the penetrating tip is designed with a cross section having a symmetry arranged to lie substantially on the longitudinal center line (generally Line 7) of the needle. What Baldwin fails to explicitly disclose is that such symmetry causes at least three substantially equally sized forces in different directions which are radial to the longitudinal center line of the needle and which forces counteract each other so that the needle will tend not to deviate from the initial penetration direction when the needle penetrates a membrane. However, it is held that the configuration of the needle of Baldwin would necessarily cause at least three substantially equally sized forces when penetrating a membrane because of at least the circular cross section of the proximal portion of the needle which would create an infinite number of equally distributed forces about the circumference of the needle and secondly because of the triangular cross section having rounded edges of the most distal tip. It is not possible for the Office to perform experimental testing of Applicant's claimed invention and the prior art in order to positively ascertain the exact distribution of forces. As such, Examiner must rely upon the claimed structure in order to differentiate whether or not the prior art is capable of satisfying the claimed functional language. As the prior art of Baldwin and Applicant's invention as claimed both comprise the same claimed structure, absent explicit evidence to the contrary, it is held that the prior art of Baldwin is capable of satisfying the claimed functional language.

Regarding Claims 62, 80, and 81, Baldwin discloses the pointed end of the needle such that it has a shape substantially corresponding to a part of an imaginary cone, the tip of which coincides with the substantially point-shaped edge (Figure 7).

Regarding Claims 63 and 82, Baldwin discloses that at least a major part of the opening is arranged on one and the same half of the cross section of the needle (Figures 1, 2, and 7). It is important to note that a cross section may be taken along any two points of the needle.

Regarding Claims 65 and 84, Baldwin illustrates the needle to be provided with a back bevel cut.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 64 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 3,071,135 ("Baldwin") as applied to Claims 56 or 58 above, and further in view of US Patent No. 4,958,621 ("Topel").

Regarding Claims 64 and 83, Baldwin discloses the device substantially as claimed except that the pointed end is provided with a basic shape in accordance with a lancet bevel cut. However, Topel discloses that needles are typically provided with a lancet bevel (Column 6, Lines 13-14). However, as Applicant has not disclosed that this particular configuration solves any explicitly stated problem or is anything more than one of the numerous configurations a person having ordinary skill in the art would find obvious for the purpose of beveled needle, it would have been a matter of obvious design choice for one having ordinary skill in the art at the time the invention was made to construct the device of Baldwin having a lancet bevel cut in place of the back bevel cut, as is established a ubiquitous configuration by Topel. As such only the expected results of using one notoriously well-known bevel in place of another would be accomplished.

9. Claims 66-69, 72, 73, and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 3,071,135 ("Baldwin") as applied to Claims 56, 58, or 65 above.

Regarding Claim 66-69, 72, 73, and 86, Baldwin illustrates the back bevel cut has a tip angle to the order of 50 degrees (Figure 1). While Baldwin does not disclose the exact angle it has been held that discovering the workable range or optimum value of a result effective variable involves only routine and customary skill in the art. As such,

it would have been obvious for one having ordinary skill in the art at the time the invention was made to form the back bevel cut tip angle of the device of Baldwin to be within a specific interval or value, specifically 75 degrees or 20 to 50 degrees, as a product of routine and customary experimentation to find the optimum angle for such a bevel. It is important to note that Applicant suggests a wide range of angles which contrary to explicit showing otherwise suggests no criticality to said angle.

10. Claims 70, 71, 74, 75, 85, and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 3,071,135 ("Baldwin") as applied to Claim 56, 58, 65 or 69 above, and further in view of US Patent No. 6,517,523 ("Kaneko").

Regarding Claims 70, 71, 74, 75, 85, and 87, Baldwin discloses the device substantially as claimed except for specifically disclosing the second grind angle of the back bevel cut. Additionally, Baldwin fails to illustrate the needle in an appropriate view such that an approximation of said angle may be ascertained. However, Kaneko discloses a needle (1) having a second grind angle of between at least 115 to 150 degrees depending at what point the angle is measured (Figure 1C). It has been held that discovering the workable range or optimum value of a result effective variable involves only routine and customary skill in the art. As such, it would have been obvious for one having ordinary skill in the art at the time the invention was made to form the back bevel cut tip angle of the device of Kaneko to be within a specific interval or value, specifically 100 degrees, as a product of routine and customary experimentation to find the optimum angle for such a bevel. It would have further been obvious for one having ordinary skill in the art at the time the invention was made to utilize the second grind

angle as disclosed by Kaneko, in conjunction with the device of Kaneko, thereby only providing a known value for the second grind angle. It is important to note that Applicant suggests a wide range of angles which contrary to explicit showing otherwise suggests no criticality to said angle.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM CARPENTER whose telephone number is (571)270-3637. The examiner can normally be reached on Monday through Thursday from 7:00AM-4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3767

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William Carpenter/

Examiner, Art Unit 3767

08/11/2008

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767